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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/049,227	03/27/98	REIMON M	4821-304

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EXAMINER	
DELACROIX MUIRHEI,C	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 12/22/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/049,227	REDMOND et al.
Examiner	**Group Art Unit**
Delacroix-Muirheid	1654

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☒ Claim(s) 1-35 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-35 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

DETAILED ACTION

Claims 1-35 are presented for prosecution on the merits.

Information Disclosure Statement

Applicant's Information Disclosure Statements received Aug. 31, 1998 and Sep. 2, 1998 have been considered.

Please refer to Applicant's copy of the 1449 attached herewtih.

Specification

1. The abstract of the disclosure is objected to because the abstract is not commensurate in scope with the specification. Correction is required. See MPEP § 608.01(b).

2. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. **If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement.** In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Claim Rejections - 35 USC § 112

3. Claims 12, 33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The phrase "substantially free of mono or di-saccharides/ lactose" in claims 12, 33 and 34 is relative and renders the claim indefinite. The phrase "substantially free" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claims are even more indefinite by the limitation at lines 4-5 of claims 33 and 34, where it is claimed that the pharmaceutically acceptable excipient cannot be lactose:

5. Claims 1, 13-20, 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claimed phrases "free of lactose" and "lactose-free" render the claims indefinite because the metes and bounds of the patent protection desired by said phrases are unclear. Said phrases contradict the language in the specification. On its face, the phrases "lactose free" or "free of lactose" mean there is no lactose present in the the claimed pharmaceutical compositions. Yet, in the specification, at page 15, Applicant states that lactose may be present in the claimed compositions but in amounts that won't detrimentally affect the claimed composition. Moreover, it is unclear as to what amount of lactose is acceptable and the specification does not provide a standard for ascertaining the requisite amount. Further clarification is requested.

Claim Objections

6. Claims 34 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 33. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Despite a difference in preamble language, claims 33 and 34 are identical in scope in that said claims recite identical active ingredients and pharmaceutically acceptable excipients.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 13, 14, 16-18, 21-25, 28-30, 35 are rejected under 35 U.S.C. 102(b) as being anticipated by EPA 0693281 ('281).

EPA '281 discloses pharmaceutical compositions for treating depression, wherein said compositions contain fluoxetine or an acid addition salt thereof suitable for manufacturing dispersible tablets by direct compression and further comprise appropriate excipients and coadjuvants. Specifically, the active ingredient, fluoxetine, is present in said compositions in an amount between 4% and 7.5% by weight at a dose of 20 mg. The compositions require a disintegrant and further comprise excipients and coadjuvants such as microcrystalline cellulose(46% to 58% by weight), lactose, hydroxypropyl cellulose, drying flowing starch or pregelatinized starch (60% to 70% by weight), with some of the preferred embodiments **not containing any lactose.**

EPA '281 further discloses that because dispersible tablets are sensitive to humidity and that their stability is compromised by conventional granulation techniques, direct compression techniques are preferred because direct compression is rapid and avoids degradation of the active ingredient due to hydrolysis. Please refer to the abstract; page 3, line 28 to page 4, line 28; page 5, line 22-31; Examples 2-20.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over EPA '281 in view of the Physicians Desk Reference (PDR), 50th edition (1996).

EPA '281 as applied above.

EPA '281 does not disclose pharmaceutical compositons containing an optically pure enantiomer of fluoxetine; however, the Examiner refers to the teaching in PDR, page 919, under CLINICAL PHARMACOLOGY, Enantiomers, wherein it is stated that both the R- and S- enantiomers of fluoxetine are specific and potent serotonin uptake inhibitors.

It would have been obvious to one of ordinary skill in the art to modify the pharmaceutical compositions of EPA '281 to contain optically pure enantiomers of fluoxetine because PDR further discloses that the R- and S- enantiomers of fluoxetine have essentially equivalent pharmacologic activity. Thus, such a modification would have been motivated by the reasoned expectation of successfully producing an equally effective pharmaceutical product.

With respect to not using a disintegrant in the claimed compositions, this is obvious and well within the capability of the skilled artisan.

12. Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over EPA '281 in view of PDR as applied to claims 1-35 above, and further in view of Wirth et al.

EPA '281 and PDR as applied above.

EPA '281 does not disclose that the preferred embodiment (Ex. 1) should not contain lactose as one of the excipients; however, the Examiner further relies upon Wirth et al., which discloses that the presence of lactose in pharmaceutical compositions containing fluoxetine causes fluoxetine to undergo the Maillard reaction producing unwanted degradation products. Please refer to the abstract.

It would have been obvious to one of ordinary skill in the art to modify the fluoxetine compositions of Ex. 1 in EPA '281 to **not** contain lactose because Wirth discloses that the presence of lactose compromises the stability of said fluoxetine compositions, thus leading one of ordinary skill in the art away from choosing lactose as an excipient in fluoxetine compositions. See abstract.

Conclusion

Hence, claims 1-35 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on (703) 308-0254. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM

Dec. 20, 1998

Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600